Billing Code

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Deepak Kaushal, Ph.D. (Respondent), Professor and Director, Southwest National Primate Research Center, Host Pathogen Interactions Program, Texas Biomedical Research Institute (TBRI). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grants U19 AI111211, R01 AI111943, R01 AI123047, R01 AI134240, K24 AI058609, and K24 AI114444, and Office of the Director, NIH, grants P51 OD011104 and P51 OD011133. The administrative actions, including supervision for a period of one (1) year, were implemented beginning on July 22, 2022, and are detailed below.

FOR FURTHER INFORMATION CONTACT:

Wanda K. Jones, Dr.P.H.
Acting Director
Office of Research Integrity
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SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Deepak Kaushal, Ph.D., Texas Biomedical Research Institute: Based on the report of an inquiry conducted by TBRI, Respondent's admission, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Deepak Kaushal, Professor and Director, Southwest National Primate Research Center, Host Pathogen Interactions Program, TBRI, engaged in research misconduct in research supported by PHS funds, specifically NIAID, NIH, grants U19 AI111211, R01 AI111943, R01 AI123047, R01 AI134240, K24 AI058609, and K24 AI114444, and Office of the Director, NIH, grants P51 OD011104 and P51 OD011133.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and fabricating the experimental methodology to demonstrate results obtained under different experimental conditions that were included in the following one (1) published paper and two (2) grant applications submitted for PHS funds:

- Isoniazid and Rifapentine Treatment Eradicates Persistent Mycobacterium tuberculosis in Macaques. *Am J Respir Crit Care Med*. 2020 Feb 15;201(4):469-77; doi: 10.1164/rccm.201903-0646OC (hereafter referred to as "*Am J Respir Crit Care Med* 2020"). Retraction in: *Am J Respir Crit Care Med*. 2021 Apr 15;203(8):1045; doi: 10.1164/rccm.v203retraction1.

- R01 AI159898-01, "Effect of latent TB infection on immunity to M. tuberculosis reinfection," submitted to NIAID, NIH, on June 25, 2020.

- R01 AI147947-01A1, "Effect of prior latent TB infection on immune responses to M. tuberculosis," submitted to NIAID, NIH, on July 18, 2019.

Specifically, ORI found that Respondent knowingly, intentionally, or recklessly:

- falsified and fabricated the numbers for treated and untreated non-human primates (NHP) used in the study. The experimental design in *Am J Respir Crit Care Med* 2020 falsely stated that seven NHPs were treated with 3HP (i.e., a treatment regimen constituting of twelve once-weekly doses of 15 mg/kg isoniazid [INH] and 15 mg/kg rifapentine [RPT]) and another seven NHPs were untreated controls, when instead a total of eight NHPs were treated with INH and RPT and six NHPs were untreated controls.

- falsified and fabricated the number of weekly doses of INH and RPT treatment administered to NHPs in the study. The experimental design in *Am J Respir Crit Care Med* 2020 falsely stated that seven NHPs were treated with 3HP, when instead the NHPs were treated with a variable number of INH and RPT doses that do not conform to the 3HP regimen.

- falsified and fabricated the time interval between mycobacterium (Mtb) exposure and the first dose of INH and RPT treatments that were administered to NHPs in the study. The experimental design in *Am J Respir Crit Care Med* 2020 falsely stated that seven NHPs were treated with 3HP beginning in Week 16-18 after Mtb infection, when instead the treated NHPs received the first dose of INH and RPT treatment at different time points.

- falsified and fabricated the time interval between the last weekly doses of INH and IPT treatment and infection with simian immunodeficiency virus (SIV). The experimental design in Figure 3A of *Am J Respir Crit Care Med* 2020 falsely stated that after treatment with weekly INH and RPT for three months, NHPs were rested for one month before coinfection

with SIV, when instead the treated NHPs were infected with SIV either on the same day as the last dose of INH and RPT treatment or at a different time point.

- included survival kinetics data from the falsified 3HP treatment in Figure 1G of *Am J Respir Crit Care Med* 2020 as Figure 5 of R01 AI159898-01 to demonstrate the efficacy of 3HP treatment against reactivation of latent Mtb infection in NHPs post SIV infection.

- included bacterial persistence and burden data from the falsified 3HP treatment in Figures 2A, 2B, and 2C of *Am J Respir Crit Care Med* 2020 as Figure 6C of R01 AI159898-01 and Figure 2 of R01 AI147947-01A1 to represent the efficacy of 3HP treatment in reducing Mtb burden in NHPs post SIV infection.

- included pulmonary pathology data from the falsified 3HP treatment in Figures 3A and 3B of *Am J Respir Crit Care Med* 2020 as Figures 6A and 6B, respectively, of R01 AI159898-01 to represent the efficacy of 3HP treatment against reactivation of latent Mtb infected NHPs post SIV infection.

- included clinical parameters from the falsified 3HP treatment in Figure 1 of *Am J Respir Crit Care Med* 2020 as Figure 1 of R01 AI147947-01A1 to present clinical correlates of latent Mtb infection and SIV induced reactivation under 3HP treatment.

- included pulmonary pathology data from the falsified 3HP treatment in Figure 3 of *Am J Respir Crit Care Med* 2020 as Figure 3 of R01 AI147947-01A1 to represent efficacy of 3HP treatment in reducing lung pathology due to reactivation of latent Mtb infection in NHPs post SIV infection.

- included untreated NHP's lung tissue immunohistochemistry image representing CD3-positive T-cell staining from Figure 4B of *Am J Respir Crit Care Med* 2020 as Figure 6A of R01 AI147947-01A1 to represent CD3-positive T-cell staining in lung tissue of 3HP treated NHPs.

Dr. Kaushal entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed to the following:

(1) Respondent will have his research supervised for a period of one (1) year beginning on July 22, 2022 (the "Supervision Period"). Prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity in PHS-supported research, Respondent will submit a plan for supervision of Respondent's duties to ORI for approval. The supervision plan must be designed to ensure the integrity of Respondent's research. Respondent will not participate in any PHS-supported research until such a supervision plan is approved by ORI. Respondent will comply with the agreed-upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2-3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of one (1) year from the effective date of this Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month intervals setting forth the committee meeting dates and Respondent's

compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application, report, manuscript, or abstract are supported by the research record.

(3) During the Supervision Period, Respondent will ensure that any institution employing him submits, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported and not plagiarized in the application, report, manuscript, or abstract.

(4) If no supervision plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the Supervision Period that his participation was not proposed on a research project for which an application for PHS support was submitted and that he has not participated in any capacity in PHS-supported research.

(5) During the Supervision Period, Respondent will exclude himself voluntarily from serving in any advisory or consultant capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee.

Dated: August 3, 2022.

Wanda K. Jones,

Acting Director,
Office of Research Integrity,

Office of the Assistant Secretary for Health.

[FR Doc. 2022-16946 Filed: 8/5/2022 8:45 am; Publication Date: 8/8/2022]